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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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TENA [illegible]
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EXAMINER	
[illegible]	

ART UNIT	PAPER NUMBER
1651	3

DATE MAILED: 04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/754,205	GELBER ET AL.	
	Examiner	Art Unit	
	Brett T Ozga	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-130* is/are pending in the application.

4a) Of the above claim(s) *1-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-130* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 USC 121:

I. Claims 1-65, drawn to compositions for treating an immune response of the respiratory system, classified in class 424, subclass 725.

II. Claims 66-130, drawn to methods for treating an immune response of the respiratory system, classified in class 424, subclass 725.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are methods for treating an immune response of the respiratory system in which one does not use the compositions of Group I, and instead uses codeine.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Terry Kramer on 3/19/01, a provisional election was made with traverse to prosecute the invention of Group II, claims 66-130. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-65 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Addition of "administering" after comprising in claim 66 is recommended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 66-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Product Alert (14 Jun 1993) in view of Cuca et al. (USP #5858391), Wood et al. (USP #5260066), Derwent 1997-449418 and Patwardhan (USP #5494668).

The instant application's first independent claim is a method of treating a cough comprising at least one pharmaceutical and nutraceutical wherein at least one treats an immune response of the respiratory system and an acceptable base. Dependent claims further limit by making the immune response cause a coughing reflex and the cough suppressant is dextromethorphan or expectorant as guaifenesin. They further limit by selecting the decongestants from a group including phenylpropanolamine, selecting the immune booster nutraceutical from a group including Goldenseal and selecting the anti-oxidant from a group including garlic.

Further limitations include wild cherry bark as the cough reflex-sedating agent.

Product Alert teaches a method of treating a cough comprising wild cherry bark and Goldenseal. (See abstract) Product Alert does not teach dextromethorphan or guaifenesin. It also does not teach the nutraceutical liver protectant as milk thistle. Also, it does not teach phenylpropanolamine, pseudoephidrine, ephedrine, phenylephrine, naphazoline, oxymetazoline, tetrahydrozoline, xylometazoline, propylhexedrine and L-desoxyephedrine as a decongestant. Product Alert also does not teach that immune stimulation is inherently positive.

Cuca et al. teach dextromethorphan as cough suppressants and guaifenesin as expectorants in a method of treating a cough. (See col. 8, first paragraph)

Wood et al. teach phenylpropanolamine, pseudoephidrine, ephedrine, phenylephrine, naphazoline, oxymetazoline, tetrahydrozoline, xylometazoline,

propylhexedrine and L-desoxyephedrine as decongestants in a method of treating a cough.

Derwent teaches garlic used to cure coughs. (See abstract).

Patwardhan teaches that immune stimulation is inherently positive. He also teaches that use of pharmacologically active plant extracts is well known. (See col. 2, last paragraph)

Examiner takes Official Notice that the applicant's claimed immune boosters, antioxidants, pharmaceuticals and nutraceuticals are well known in the art.

The motivation to combine the references is that each composition can treat a specific cough- causing condition; combining them gives more general coverage. Also, synergism of the compositions and decrease of any deleterious effects gives one motivation to combine.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers

for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

FRANCISCO PRATS
PRIMARY EXAMINER